

REMARKS/ARGUMENTS

The May 30, 2003 Office Action has asked Applicants to clarify their response to the restriction requirement, objected to claim 21 and rejected all pending claims under 35 U.S.C. § 102(b). In light of the amendments above and the arguments below, Applicants respectfully request reconsideration.

Restriction Requirement

Applicants clarify that claims 1 – 6, 21 and 25 are elected. Applicants thank the Examiner for the opportunity to clarify this selection.

Claim Objection

The Office Action has objected to claim 21 due to the inclusion of subject matter from non-elected claims. Applicants have amended claim 21 so that it is now drawn to computer readable mediums pertaining to the method of claim 1.

§ 102 Rejections

Claims 1 – 6 and 25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Eisen, et al. The Examiner cites Eisen as disclosing “a method for determining the relationship among physiological determinants such as genes.”

Applicants contest the Examiner’s characterization of Eisen, et al. and assert that the “physiological determinants” of Applicants’ claims are not equivalent to gene expression analysis described by Eisen, et al. Applicants’ method is not drawn to relationships within gene expression profiles but is instead drawn to the examination of physiological traits. Applicants draw the Examiner’s attention to the specification, page 2 beginning at line 16.

Applicants have amended the claims to refer to “traits” to clarify this aspect of Applicants’ invention.

As described in Eisen, et al., the study involves a cluster analysis and displays gene expression data determined using a microarray (gene chip) study. The cluster analysis assigns genes to presumed “functional” groupings. It should be noted that these functional groupings are inferred and not actually tested as part of this manuscript. In effect, this study is an association study—the genes that have the same expression pattern are inferred to have the same function.

In the present invention, Applicants are not using any gene expression data but rather independent physiological measurements. In the analogy of the gene chips, each of physiological measurements might be thought to be equivalent to a single location on the chip. This extension is not a simple step in logic. Indeed, physiological correlations are typically only made when there is a known relationship between the physiological traits (see Exhibit A, Summary, page 142 second sentence of the second paragraph). For example, correlations between body weight and blood pressure are considered acceptable, whereas correlations between eye color and blood pressure are not. In the method of the present invention, one would accept the correlation between eye color and blood pressure if this correlation were changed by a treatment (genetic, drug or surgical). This is unique to the present invention.

Eisen, et al. and the present invention can also be distinguished by Eisen, et al.’s use of clustering algorithms. Eisen, et al. uses a hierarchical clustering algorithm. In the present invention, any form of cluster analysis is acceptable. The goal is similar to Eisen—to assign similarity using a statistical approach. However, the types of data being used are quite distinct, as is the analysis. Applicants first conduct a regression analysis to determine the

relationship between the different physiological estimates. The results are then clustered.

Eisen, et al. simply cluster on the expression data—which is not a physiological measurement. We began our cluster analysis with an analysis using linear regression. Once completed the data were data were clustered based on presumed physiological relationships, e.g., which traits were similar to each other.

The Examiner comments that “Figure 2 [of Eisen, et al.] discloses a color-coded graphical matrix.” In the present invention, the application of color-coding is novel in that it shows a continuum of colors each representing a correlation coefficient value. This color coding with the cluster analysis in a matrix showing all comparisons is not equivalent to Eisen, Figure 2, which shows the use of only two colors representing direction of expression sorted by the cluster analysis. It does not result in the showing of each element versus all the other elements, as does the strategy of the present invention. Note that claim 3 contains a limitation of “constructing a colored clustered correlation matrix using a plurality of colors, wherein in each color indicates a selected degree of correlation, and wherein patterns of colors in said clustered correlation matrix are used to identify said relationships.” Eisen, et al. does not teach the use of color to “indicate a selected degree of correlation” or use “cluster correlation matrix . . . to identify said relationships.”

The Office Action notes that “the source of physiological determinants is 8600 distinct human transcripts.” As Applicants have emphasized above, a human transcript is not a physiological determinant in the present invention. A human transcript is the product of DNA transcription and is not a “physiological trait.”

Claims 1 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Enright, et al. The Examiner cites Enright, et al. as disclosing

“ . . . a method for using a computer program, GeneRace, written in ANSI C, and developed on a Sun Ultra workstation . . . as in claim 21. The method of Enright comprises using a recursive single-linkage clustering of the corrected matrix to allow efficient and accurate family representation for each protein in the dataset . . . and for multi-domain proteins of two clusters of are artefactually linked [sic] . . . as in claim 1, steps (a)-(d).”

Enright, et al. have generated a computer program for clustering large protein sequence data sets. The only similarity between the program of the present invention and Enright is that both use a computer to conduct the analysis. The differences include: (1) different data sets [protein sequence versus physiological measurements]; and (2) providing an algorithm for predicting sequence similarity [Enright] versus a tool to create the correlation coefficients and then build the correlation matrix based on the cluster algorithm employed. The Enright program is as similar to the present invention as the Windows operating system to the PDA operating system.

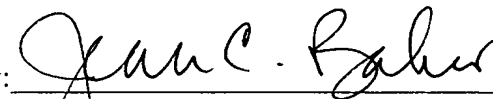
Applicants believe all pending claims to be in condition for allowance and respectfully request allowance. A Petition and Fee for Three Months Extension of Time is enclosed. No other fees are believed necessary to enter this amendment. However, if any other fees are necessary please charge Deposit Account 17-0055.

Respectfully submitted,

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